SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Hydrocodone Bitartrate and Acetaminophen (HBAP-S) Oral Solution 7.5 mg/325 mg per 15 mL (CII), 118 ml, 4 oz. Bottle	NDC 64950-343-11
Hydrocodone Bitartrate and Acetaminophen (HBAP-S) Oral Solution 7.5 mg/325 mg per 15 mL (CII), 473 ml, 16 oz. Bottle	NDC 64950-343-16
Hydrocodone Bitartrate and Acetaminophen (HBAP-S) Oral Solution 7.5 mg/325 mg per 15 mL (CII), 5 mL cup	NDC 64950-343-05
Hydrocodone Bitartrate and Acetaminophen (HBAP-S) Oral Solution 7.5 mg/325 mg per 15 mL (CII), 10 mL cup	NDC 64950-343-10
Hydrocodone Bitartrate and Acetaminophen (HBAP-S) Oral Solution 7.5 mg/325 mg per 15 mL (CII), 15 mL cup	NDC 64950-343-15
Hydrocodone Bitartrate and Acetaminophen (HBAP-S) Oral Solution 7.5 mg/325 mg per 15 mL (CII), 40 count case of 15 mL cup	NDC 64950-343-45
Hydrocodone Bitartrate and Acetaminophen (HBAP-S) Oral Solution 7.5 mg/325 mg per 15 mL (CII), 50 count case of 15 mL cup	NDC 64950-343-50

Recommended use: Hydrocodone Bitartrate and Acetaminophen (HBAP) CII Oral Solution (OS) is a narcotic medicine that works for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Restrictions: HBAP is contraindicated for patients who are hypersensitive to Hydrocodone Bitartrate and Acetaminophen, or significant respiratory depression. HBAP exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death.

Manufacturer Name: Genus Lifesciences Inc.
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Allentown, PA 18102

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SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

The product Hydrocodone Bitartrate and Acetaminophen (HBAP) CII OS is a non-hazardous pharmaceutical mixture and does not meet OSHA's Hazard Communication Standard (HCS) 2012, 29CFR 1910.1200 and OSHA's Globally Harmonized System (GHS) hazard criteria. As per OSHA section 1910.1200(b)(6)(vii), "Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient; drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment" are exempt.

The GHS hazards listed below are for the active product ingredient (API), Hydrocodone Bitartrate CII and not for the OS product itself.

Physical hazards:	Not classified
Health hazards:	Acute Oral Toxicity Category 2 Cardiovascular System and Central Nervous System category 3 Narcotic Effects
Environmental hazards:	Not classified

Signal Word: Warning

Hazard Statement: This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment. This product active ingredient, Hydrocodone, is a stimulant and a narcotic, and is a DEA Schedule II controlled substance. Substances in the DEA Schedule II have a high potential for abuse which may lead to severe psychological or physical dependence.

Pictogram:

Precautionary Statement: Generally safe at recommended doses. Because of risks of addiction, abuse, and misuse with opioids, reserves the product for use in adult patients. Accidental ingestion of large amounts may be fatal. May be habit forming. Tolerance may develop upon repeated administration. Seek medical attention is case of accidental exposure or overdose.

Contact local state professional licensing board or state controlled substances authority for information on how to prevent and detect addiction, abuse, misuse, or diversion of this product.

Hazards Not Otherwise Classified: Common effects may include light-headedness, dizziness, sedation, nausea and vomiting.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*

Chemical Identity	Other Names	CAS Number
70% Sorbitol Solution, USP	L-Sorbitol; Sorbo, Esasorb, Glucitol,	50-70-4
Acetaminophen (Active)	APAP	103-90-2
Alcohol	Ethanol, Ethyl Alcohol	64-17-5
Citric Acid Anhydrous, USP	N/A	77-92-9
D&C Red #33	Acid fuchsine D	3567-66-6
Ethyl Maltol	Veltol plus	4940-11-8
FD&C Red #40	Allura, C.I Food Red 17	25956-17-6
Glycerin	Glycerol	56-81-5
Hydrocodone Bitartrate (Active)	Dihydrocodeinone (–)-Hydrocodone	143-71-5
Methylparaben, NF	Methyl p-hydroxybenzoate	99-76-3
Propylene Glycol	1,2-Propylene glycol	57-55-6
Propylparaben, NF	Propyl p-hydroxybenzoate, Nipasol	94-13-3
Purified Water, USP	N/A	7732-18-5
Saccharin Sodium	N/A	128-44-9
Sucrose, NF	Sugar; Saccharose	57-50-1

* Chemical exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 – FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Remove contact lenses if worn. Seek medical attention if irritation or discomfort persists.

Skin Contact: Wash with soap and large amount of water. Contact medical personnel if irritation persists.

Ingestion: This product is intended for ingestion. If an overdose, taken not as prescribed, or an accidental ingestion of large amounts occurs, call a physician or a Poison Control Center (1-800-222-1222) immediately.

Inhalation: Not an expected route of exposure. If breathing is difficult, move to fresh air and seek medical attention.

Symptoms or effects: The most common side effects include light-headedness, dizziness, sedation, nausea and vomiting. The frequency of these reactions depended on several factors, including clinical setting, the patient's level of opioid tolerance, and host factors specific to the individual. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.

Recommendations: Immediate medical attention is required if an overdose is suspected. Call a Poison Control Center (1-800-222-1222) if you feel unwell. Always use a calibrated measuring device, like a dropper, when administering Hydrocodone Bitartrate and Acetaminophen OS to ensure the dose is measured and administered accurately. A household teaspoon is not an accurate measuring device and such use could lead to overdose and serious adverse reactions.

Note to Physician: Ensure accuracy when prescribing, dispensing, and administering Hydrocodone Bitartrate and Acetaminophen OS to avoid dosing errors due to confusion between mg and mL, and with other different concentrations, which could result in accidental overdose and death. Ensure the proper dose is communicated and dispensed. When writing prescriptions include both the total dose in mg and in volume. Health care providers should recommend a dropper that can measure and deliver the prescribed dose accurately, and instruct caregivers to use extreme caution in measuring the dosage. Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals. Initiate the dosing regimen for each patient individually; taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse. Follow patients closely for respiratory depression, especially within the first 24-72 hours of initiating therapy and following dosage increases, and adjust the dosage accordingly. Discuss the availability of naloxone for the emergency treatment of opioid overdose with the patient and caregiver and assess the potential need for access to naloxone, both when initiating and renewing treatment.

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing media Use Water, Dry chemical, CO_2 or any material appropriate for fire in the surrounding area. Do not use water jet as an extinguisher, as this might spread the fire.

Specific hazards arising from the mixture: None known, however gases hazardous to health might be formed (Refer to section 10)

Advice to the firefighters: Wear appropriate protective clothing and equipment, including self-contained breathing apparatus.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions: Clean the spill if is safe to do so. Minimize exposure.

Protective Equipment: Use containment equipment to prevent access to drains and sewer, such as spill blockers, dry absorbent, drain covers, and absorbent pads or socks. Safety Glasses, goggles, gloves, and protecting clothes are recommended. (Refer to section 8)

Emergency procedures: Evacuate the area. Keep unnecessary personnel away. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Containment Precautions: Isolate area around spill as specified by site procedures. Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

Clean Up Procedures: Collect spill with suitable absorbent material, broom and scoop, and place it in a clearly labeled compatible container for waste. Decontaminate the area with water. Notify the manager in charge of DEA affairs to inform the spill and for instructions on how to dispose the material as a controlled substances waste. Dispose according to applicable regulations (Refer to section 13).

SECTION 7 – HANDLING AND STORAGE

Precaution for safe handling: Observe safe industrial practices. No special handling requirements for normal use of this material. Wash hands thoroughly after handling. Wear protective clothing when handling large quantities.

Conditions for safe storage: Store upright in the original container with child resistant closure tightly secured at controlled room temperature of 20°C to 25°C (68° to 77°F). Keep out of reach of children. For more information, follow as directed in product packaging. Location of storage must comply with DEA regulations.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

There is no exposure limits for the OS products. The exposure limits listed below are for the active product ingredient (API) Hydrocodone CII and not for the OS product itself.

OSHA Permissible Exposure Limits (PELs):	None
Occupational Exposure Limit (OEL's):	15 µg/m^3
Acceptable Daily Exposure (ADE):	70 µg/day
5 Band System Exposure Classification:	Category 3 – High Risk
ACGIH Threshold Limit Values (TLVs):	
Short Term Exposure Limits (STEL) – 15 min:	100 mg/m^3
Time Weight Average (TWA) – 8 Hours:	33 mg/m^3
NIOSH Immediately Dangerous to Life or Health (IDLH):	None

Engineering Controls: Not required when handling liquid or containers. Good ventilation should be use. Ventilation should be matched to conditions.

Personal Protective Measures:

Respiratory protection:	None required when handling liquids.
Eye protection:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Protective gloves:	Not required under normal conditions of use. Chemical compatible when needed.
Skin and body protection:	Not required under normal conditions of use. Wear protective clothing when and if working with large quantities.
Hygiene measures:	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking.
Other personal protection:	None required

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Appearance:	Red colored liquid	Odor:	Tropical fruit punch
Density:	1.17 g/ml	Boiling Point:	Not available
Melting Point:	Not Applicable	Solubility:	In water
Viscosity:	Not Available	Specific Gravity:	Not Available
Evaporation Rate:	Not Available	Conductivity:	Not Available

Chemical Properties:

pH:	3.5 – 5.5	Flash Point:	Not Available
Reactivity:	Refer to section 10	Toxicity:	Refer to section 11

SECTION 10 – STABILITY AND REACTIVITY

Reactivity: None expected under normal conditions of use.

Chemical stability: Stable under normal conditions of use.

Other:

Conditions to avoid:	Excessive cold, freezing. Contact with incompatible materials.
Incompatible materials:	As a precautionary measure, keep away from strong oxidizers and acids.
Hazardous decomposition products:	Carbon and Nitrogen Oxides

SECTION 11 – TOXICOLOGICAL INFORMATION

Routes of exposure: Oral, Ingestion

Delayed, immediate and chronic effects for short and long term exposure:

General effects: Have potential for abuse, misuse, and dependence. It may cause nervous system disorders. In a patient physically dependent on opioids may lead to a withdrawal syndrome and return of pain. Digestion of food in the small intestine might be delayed. Release manifestations may include pruritus, flushing, red eyes, sweating, low blood pressure, anaphylaxis, and/or orthostatic hypotension.

Sensitization: Not a respiratory sensitizer

Mutagenic effects: Mutagenicity studies have not been conducted; however, published information is available for the individual active ingredients or related active ingredients.

Reproductive toxicity: Fertility and reproductive studies have not been conducted; however, published information is available for the individual active ingredients or related active ingredients. Inform patients that chronic use of opioids may cause reduced fertility.

Fetotoxic / Teratogenic Effects: There are no available data in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Prolonged use of opioid analgesics during pregnancy for medical or nonmedical purposes can result in physical dependence in the neonate and neonatal opioid withdrawal syndrome shortly after birth.

Specific Target Organ Toxicity (STOT):

Single exposure: No data available

Repeated exposure: No data available

Toxicity (LD50):

Toxicity studies have not been conducted with the Hydrocodone Bitartrate and Acetaminophen (CII) Oral Solution products. The exposure limits listed below are for the active product ingredient (API) Hydrocodone CII and not for the Oral Solution (OS) product itself.

Oral LD_{50} Rat: 375 mg/kg

Subcutaneous LD_{50} Rat: 150 mg/kg

Subcutaneous LD_{50} Mouse: 86 mg/kg

Symptoms / Adverse Reactions: The common adverse reactions are light-headedness, dizziness, sedation, anxiety, drowsiness, euphoria, fear, impairment of mental and physical performance, mental clouding, sedation, mood changes, psychological dependence, nausea and vomiting. The frequency of these reactions depended on several factors, including clinical setting, patient's level of opioid tolerance, and host factors specific to the individual.

Carcinogenicity: Carcinogenicity studies have not been conducted; however, published information is available for the individual active ingredients or related active ingredients. Not listed as a carcinogen by OSHA.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects): Environmental properties have not been thoroughly evaluated for the product. Releases to the environment should be avoided.

Persistence and Degradability: No data available

Bioaccumulation: No data available

Leaching studies: Not Available. Expected to be slightly to moderately mobile in soil.

Other adverse effects: The pharmaceutical product is not classified as environmentally hazardous. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal; is highly recommended to avoid environmental releases.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers: Dispose used or contaminated containers in accordance with Drug Enforcement Administration (DEA) guidelines and the federal, state or local regulatory requirements.

Waste Disposal Methods: Dispose of waste in accordance with Drug Enforcement Administration (DEA) guidelines and the federal, state or local regulatory requirements.

Special Precautions: Discard away from children’s reach. Releases to the sewer and the environment should be avoided.

SECTION 14 – TRANSPORT INFORMATION

USDOT - Department of Transportation:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under USDOT.

ICAO - International Civil Aviation Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under ICAO.

IATA - International Air Transport Association:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IATA.

IMDG/IMO - International Maritime Dangerous Goods / International Maritime Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IMDG/IMO.

Special Precautions: None Known

SECTION 15 – REGULATORY INFORMATION

Drug Enforcement Administration (DEA): Listed as Schedule II Controlled Substances (CII).

Food and Drug Administration (FDA): Approved prescription medication.

Occupational Safety and Health Administration (OSHA):

GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

SARA 302/304 Extreme Hazardous Substances (EHS): Not Listed

SARA 311/312 Hazard Categories:

Immediate Hazard – No
Delayed Hazard – No
Fire Hazard – No
Pressure Hazard – No
Reactivity Hazard – No

SARA 313 Toxic Chemical Release Inventory (TRI): Not Regulated

Resource Conservation and Recovery Act (RCRA): No Code Applicable

Clean Water Act (CWA):

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Clean Air Act (CAA):

This product does not contain any chemicals listed under Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

Environmental Response Compensation and Liability Act (CERCLA):

Not applicable for the product. This product, as supplied, do not contains substances regulated as hazardous substances under CERCLA (40 CFR 302). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

Toxic Substances Control Act (TSCA):

Not applicable for the product. The following ingredients are included on the TSCA inventory 8(b):

Ingredient	CAS No
Sorbitol Solution	50-70-4
Acetaminophen	103-90-2
Alcohol	64-17-5
Citric Acid Anhydrous	77-92-9
D&C Red #33	3567-66-6
FD&C Red #40	25956-17-6
Glycerin	56-81-5
Methylparaben	99-76-3
Propylene Glycol	57-55-6
Propylparaben	94-13-3
Purified Water	7732-18-5
Saccharin Sodium	128-44-9
Sucrose	57-50-1

There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Creation Date: Jan/07/21, New SDS

Revision Date: Nov/01/21

This Safety Data Sheet cancels and replaces all preceding SDS for this product.

Genus Lifesciences Inc. believes that the information contained herein is based on the best available data at the date of preparation. However, no warranty is expressed or implied regarding the data's accuracy and completeness. Since the use of this information and the conditions of use of this material are not within the control of Genus Lifesciences Inc., it is the user's obligation to determine the conditions of safe use of this material.

Signature Manifest

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SDS Hydrocodone Bitartrate and Acetaminophen OS - 64950

Department Approval

Name/Signature	Title	Date	Meaning/Reason
July Ortiz (JORTIZ)		29 Nov 2021, 08:28:21 AM	Approved

Regulatory Affairs Approval

Name/Signature	Title	Date	Meaning/Reason
Bill Reightler (BREIGHTLER)		29 Nov 2021, 03:03:41 PM	Approved

Quality Assurance Approval

Name/Signature	Title	Date	Meaning/Reason
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